Quarterly Progress Report

N01-NS-1-2333

Restoration of Hand and Arm Function by Functional Neuromuscular Stimulation

Period covered: October 1, 2005 to December 31, 2005

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Contract abstract

The overall goal of this contract is to provide virtually all individuals with a cervical level spinal cord injury, regardless of injury level and extent, with the opportunity to gain additional useful function through the use of FNS and complementary surgical techniques. Specifically, we will expand our applications to include individuals with high tetraplegia (C1-C4), low tetraplegia (C7), and incomplete injuries. We will also extend and enhance the performance provided to the existing C5-C6 group by using improved electrode technology for some muscles and by combining several upper extremity functions into a single neuroprosthesis. The new technologies that we will develop and implement in this proposal are: the use of nerve cuffs for complete activation in high tetraplegia, the use of current steering in nerve cuffs, imaging-based assessment of maximum muscle forces, denervation, and volume activated by electrodes, multiple degree-of-freedom control, the use of dual implants, new neurotization surgeries for the reversal of denervation, new muscle transfer surgeries for high tetraplegia, and an improved forward dynamic model of the shoulder and elbow. During this contract period, all proposed neuroprostheses will come to fruition as clinically deployed and fully evaluated demonstrations.

Summary of activities during this reporting period

The following activities are described in this report:

- *Percutaneous evaluation of nerve cuff electrodes in high tetraplegia*
- *Surgical implantation of dual stimulator system in high tetraplegia*
- *Wireless data acquisition module for use with a neuroprosthesis*

Percutaneous Evaluation of Nerve Cuff Electrodes in High Tetraplegia

Contract section:
E.1.a.i.4.4. Evaluation of single and multicontact cuffs via percutaneous leads

Introduction

This report covers percutaneous testing of cuff electrodes implanted in a subject with C1-C2 incomplete spinal cord injury. Spiral nerve cuff electrodes were implanted on four upper extremity nerves. Single-contact electrodes were placed on the axillary and suprascapular nerves to stimulate the deltoid, infraspinatus and supraspinatus. Four-contact electrodes were placed on the radial and musculocutaneous nerves to stimulated the biceps, brachialis, triceps, wrist extensors, finger extensors, supinator and some thumb muscles. The previous quarterly report presented results through the 9th week post implant including selectivity on the musculocutaneous nerve, positional stability and joint moment measurements. This quarterly report summarizes the entire percutaneous phase including long term stability, selectivity and current steering.

Methods

Weekly experiments were performed from 5 to 16 weeks post implant (Table 1).

Week	5	6	7	8	9	10	11	12	13	14	15	16
Surface EMG recruitment	X							X			X	X
Percutaneous EMG recruitment				X			X				X	
Tetanic moment measurements		X	X		X			X	X	X	X	

Table 1: Schedule of testing for subject #1.

Electromyography Recordings

Surface and percutaneous EMG recordings were used to evaluate recruitment and selectivity of each nerve. Surface twitch recruitment curves were generated using single channel, square, biphasic stimulation at different values of pulse width and pulse amplitude modulation. Percutaneous recording is more accurate than surface recording but caused some pain to the subject during needle insertion. Therefore, it was only used to evaluate selectivity because of the higher resolution of recording required to distinguish between forearm muscles. One method for improving selectivity was current steering. Current steering consists of simultaneous, subthreshold anodic stimulation during the standard cathodic stimulation. The anodic threshold of each channel was determined by manually increasing the stimulation level. Then different combinations of channels were used as the cathode and the subthreshold anode.

Moment Measurements

Tetanic stimulation (12.5 Hz) was used to measure the moment capabilities of the muscles at four pulse width values. To remove passive moments from each joint, the moment produced without stimulation was subtracted from the moment produced during stimulation. To measure elbow, wrist, and finger moments, the subject was placed in a device that consisted of 4 individual four bar linkage transducers, one for the elbow and wrist and one for each of the first two fingers. For these measurements, the shoulder was abducted 55º and horizontally flexed 60º and the elbow was flexed 90º. The wrist and fingers were straight in line with the forearm.

To measure shoulder moments, the subject was placed in a setup consisting of a JR3 force and moment transducer attached to the endpoint of the humerus with the elbow bent to 90º. The shoulder was positioned at 45º of abduction and 0º of horizontal flexion. When measuring shoulder moments, axillary and suprascapular nerves were stimulated together to obtain a more realistic measurement of functional abduction using both the deltoid and the rotator cuff muscles (Figure 1).

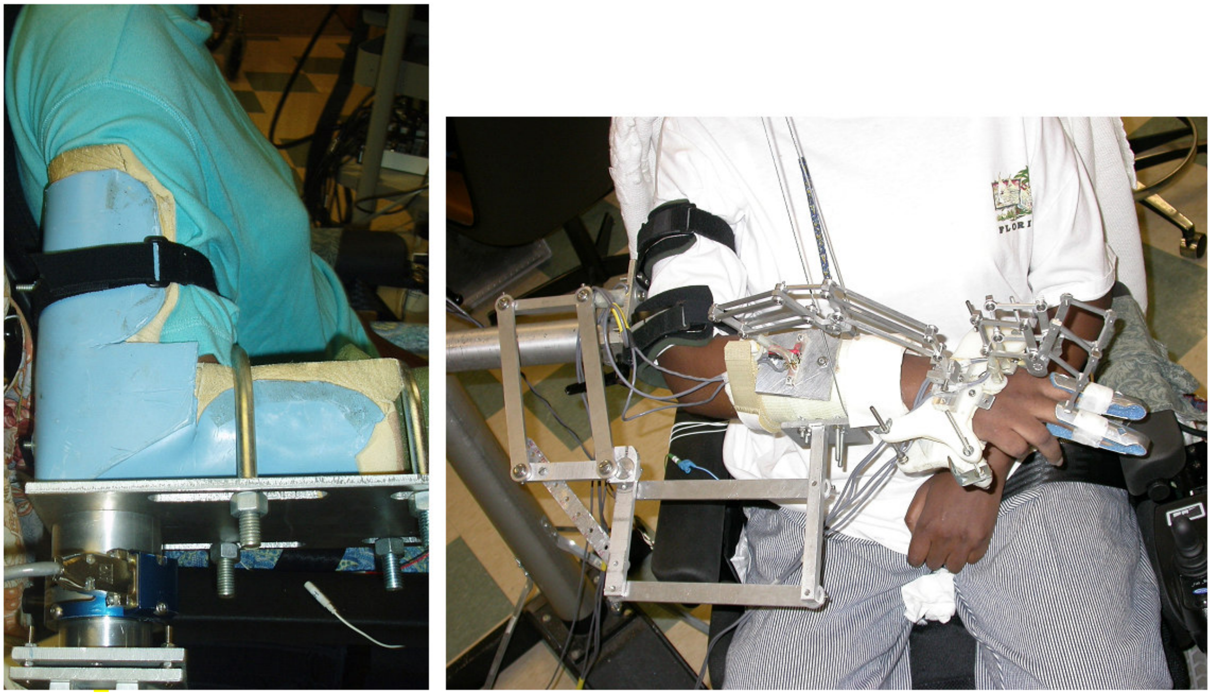

Figure 1. Pictures of moment measurement devices. Left – JR3 mounted at the end of the humerus to measure shoulder moments. Right - Four bar linkages used to measure moments at elbow, wrist and the first 2 fingers.

Since the subject tested had sensation on the area innervated by the radial and musculocutaneous nerves, one experimental session of sensory stimulation and recording was performed. First, the dermatomes were mapped by stimulating below the motor threshold and asking the subject where and what was felt. Then, tapping, brushing, squeezing or pushing stimulus was applied over the dermatomes while recording from the nerve electrode. The spiral nerve cuff electrode did not allow for bipolar recording along the nerve so bipolar recordings were made from each pair of contacts around the nerve.

Results

Electrode Positional Stability

To determine if the electrodes move during and after the surgery, the recruitment curves generated intraoperatively were compared with curves generated 5 and 16 weeks post implant (Figure 2). At both times, stimulation of channel 1 resulted in triceps activation before the other muscles while stimulation of channel 3 resulted in activation of triceps last. Qualitatively, the selectivity appears to have improved following electrode encapsulation. This indicates that intraoperative testing is a valid predictor of chronic performance.

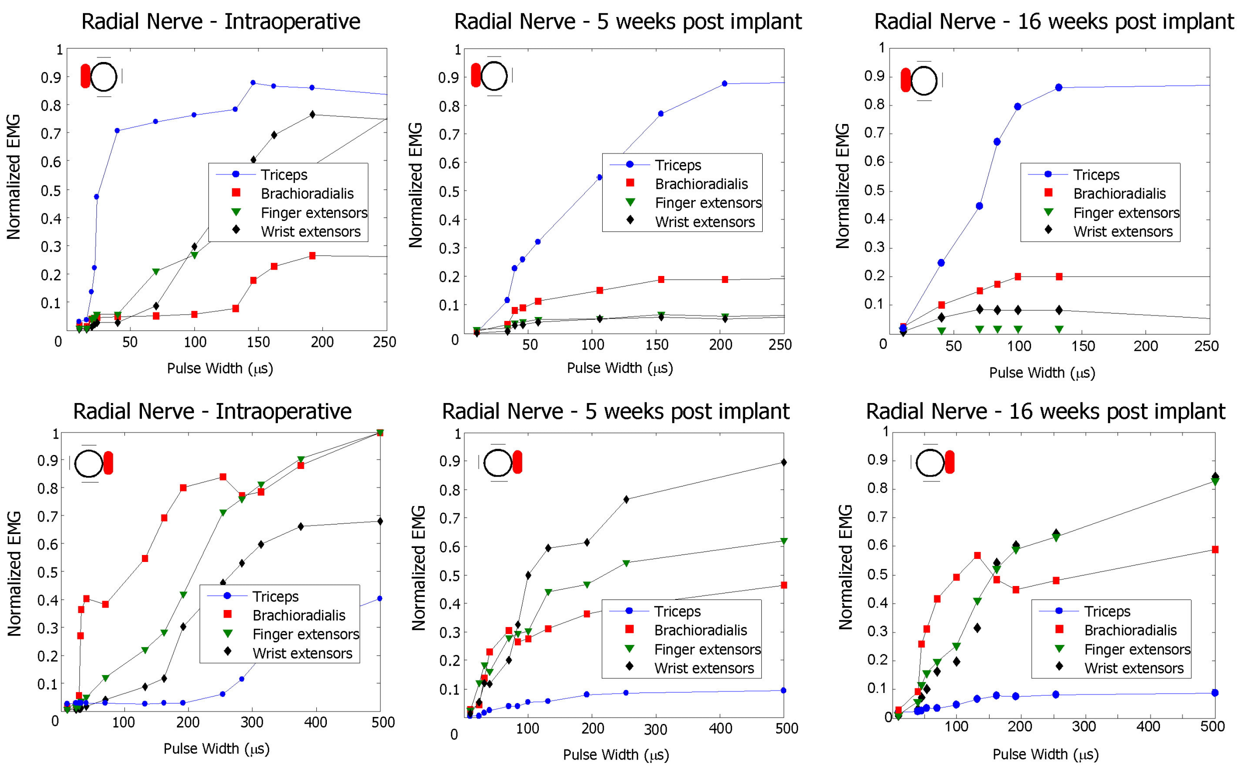

Figure 2. Comparison of radial nerve electrode recruitment from intraoperative testing to 5 and 16 weeks post implant. Each recruitment curve was generated using pulse width modulation with a pulse amplitude of 0.8 mA. The schematic in the upper left hand corner of each plot visually depicts the channel used for simulation. Channel 1 activates triceps first in each case and channel 3 activates triceps last in each case.

Moment Production

The maximum moments recorded at each session are shown in Figures 3, 4 and 5. At 14 weeks, the deltoid strength (axillary nerve-Figure 3A) significantly ($p<0.0002$) increased with exercise while the infraspinatus and supraspinatus together produced horizontal flexion moments that were not significantly different ($p=0.35$) and abduction moments that were significantly lower ($p<.02$) than the values recorded at 7 weeks. When the axillary and suprascapular nerves were stimulated together, an abduction moment of 340 N-cm was recorded.

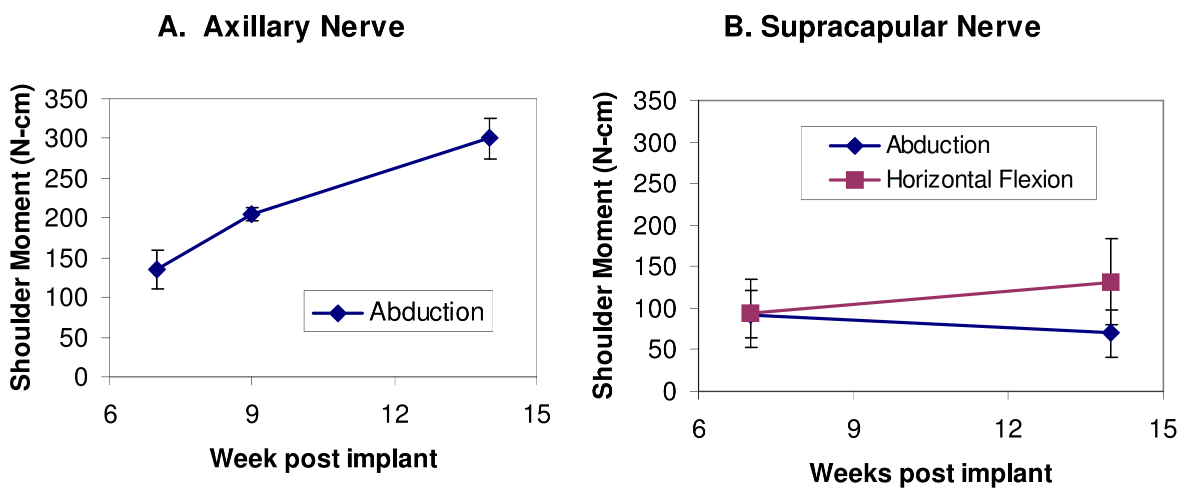

Figure 3. Shoulder moments recorded from the axillary nerve (deltoid- A) and suprascapular nerve (supraspinatus and infraspinatus- B) stimulation.

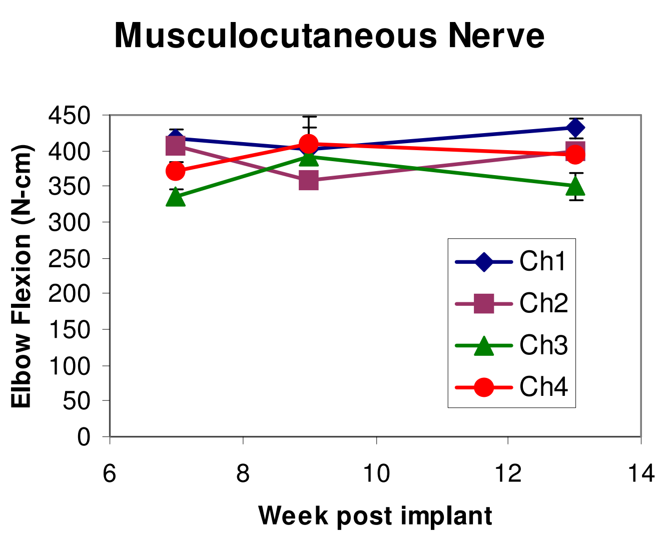

Figure 4. Elbow moment recorded from musculocutaneous nerve stimulation. Measurements were made with the elbow flexed 90º

Musculocutaneous nerve stimulation did not cause a significant increase in elbow flexion moment over the 5 weeks tested (Figure 4). There was some variability among the different contacts but it was not clinically relevant. The maximum flexion moment produced was 432 ± 14 N-cm from contact 1.

Radial nerve stimulation produced moments at the elbow, wrist and fingers (Figure 5A). Channel 1 produced solely elbow extension (Figure 2) and the force significantly increased ($p<0.00002$) across the 5 weeks tested (Figure 5A). Channel 3 produced predominantly wrist extension with some elbow flexion (brachioradialis) and the wrist moment significantly increased ($p<0.0004$) after 5 weeks (Figure 5B). Radial nerve stimulation should cause finger extension and some finger extension was seen but there was also significant finger flexion, especially on channel 4 (Figures 5C and 5D).

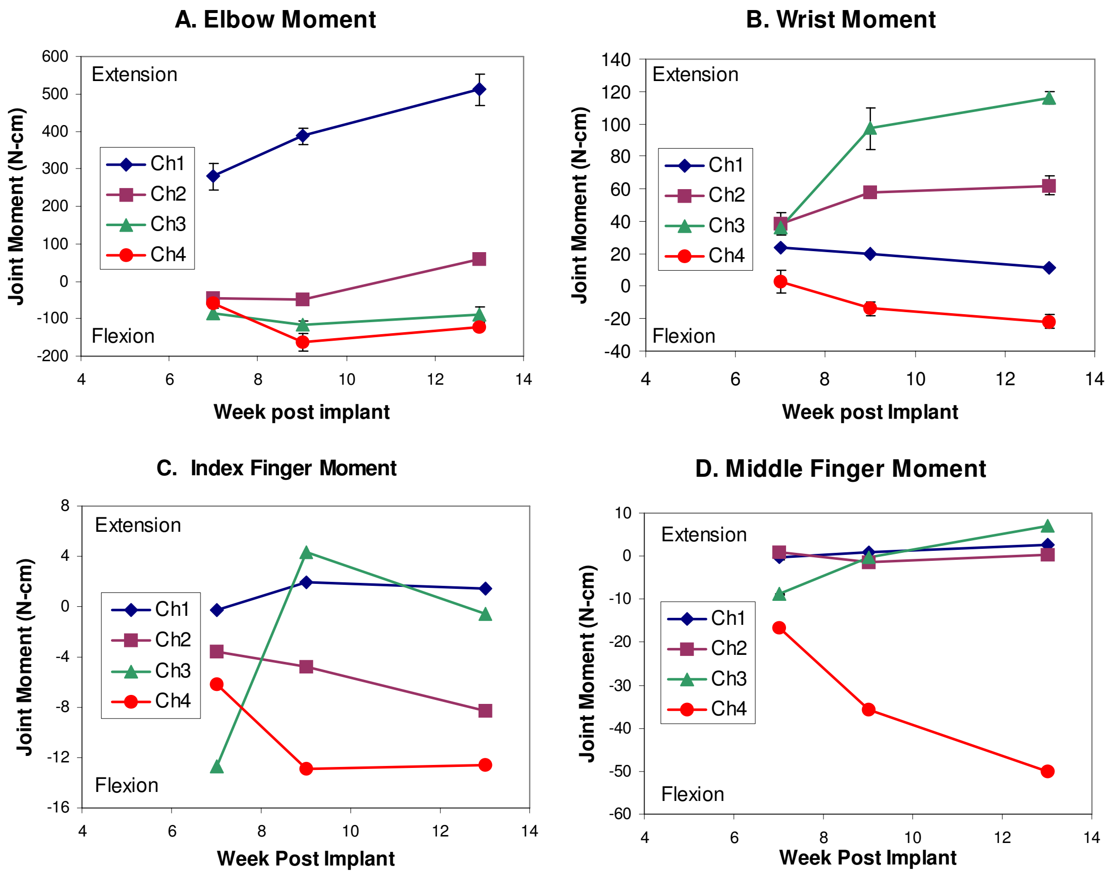

Figure 5. Joint moments measured from radial nerve stimulation. Positive Y is an extension moment and negative Y is flexion.

Current steering

Current steering was attempted to increase the selectivity on the musculocutaneous and radial nerves. On the musculocutaneous nerve, both the biceps and the brachialis could be activated separately using current steering (presented last quarter and in Figure 6). On the radial nerve, some increased selectivity was seen but nothing that was functionally significant. Cathodic stimulation of channel 1 produced solely triceps stimulation (Figure 2). Cathodic stimulation of channel 2 recruited triceps first, but not as completely as channel 1 (Figure 7A). With the addition of current steering, the triceps threshold was shifted to allow recruitment of brachioradialis, extensor carpi radialis (ECR) and supinator before triceps (Figure 7B).

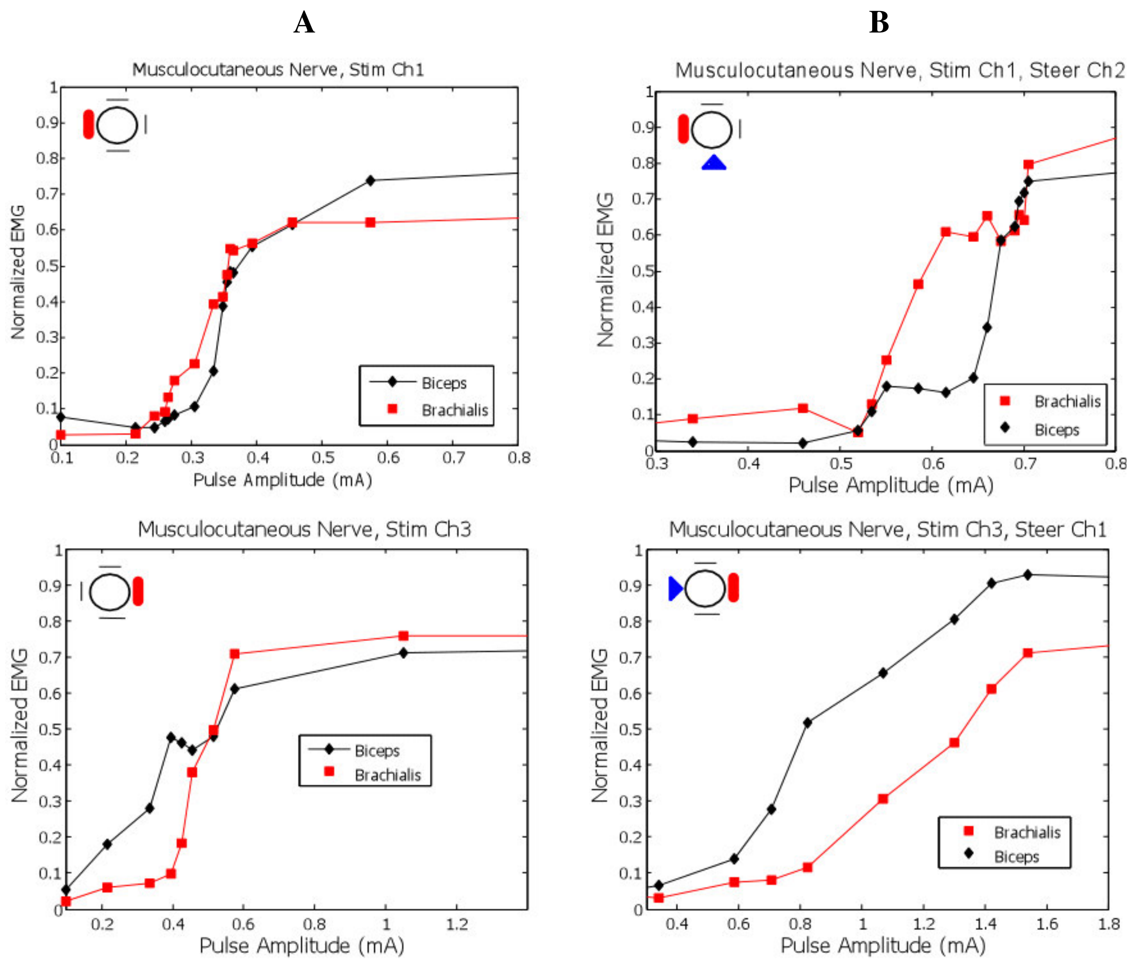

Figure 6. Pulse amplitude modulation recruitment curves from stimulating contact 1 and 3 on the

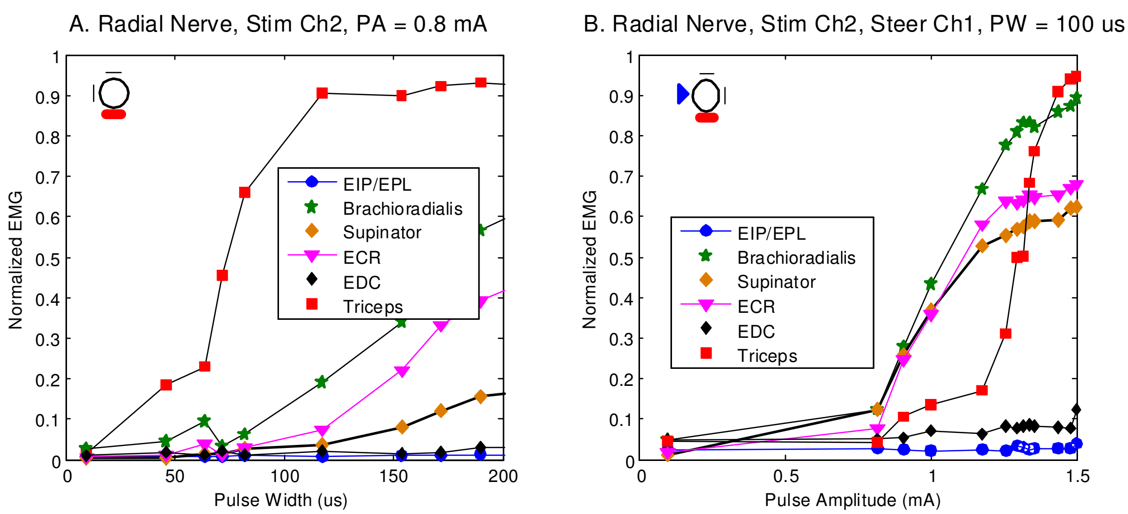

Figure 7. Effect of current steering on channel 2. Triceps was recruited first using purely cathodic stimulation. Then simultaneous anodic subthreshold stimulation was added on channel 1, the triceps was inhibited to allow the brachioradialis, extensor carpi radialis (ECR) and supinator to be recruited first.

Sensation

Sensation due to motor stimulation was not reported to be painful between threshold and supramaximal stimulation. If the stimulation levels were increased significantly beyond supramaximal, the subject would report a painful sensation. During motor threshold stimulation of the musculocutaneous nerve, the subject felt pressure over most of her forearm that increased with increasing pulse amplitude. Smaller areas of sensation could not be localized by stimulation.

Nerve recordings were also made and no obvious spike patterns were seen due to the tapping, brushing, squeezing or pushing stimuli. Analysis of this data is ongoing.

Discussion

To estimate the functionality of the shoulder abductors, the total abduction force was compared to model simulations in the same position. The model predicted that 430 N-cm were required from the deltoid to maintain the arm at 45° of abduction. The measured deltoid abduction was 300 N-cm. However, between 9 and 14 weeks, this abduction moment increased by 50%. Additional increases are expected as the subject continues to exercise and loosen the joint. The unconstrained abduction should increase with stimulation of the serratus anterior which was implanted during the stimulator implant surgery (see next report). The serratus anterior improves scapular stability as well as rotating the scapula, which should allow for easier abduction.

On the musculocutaneous nerve, current steering was able to selectively activate the biceps and the brachialis. Functionally, both of these muscles flex the elbow but the biceps also causes supination so this distinction is important. On the radial nerve, single contact stimulation was capable of functionally selectively activating the triceps and wrist extensors. In this case, the addition of current steering did little to improve the functional output since the same function produced with steering could also be produced by stimulating contact 3. To selectively activate the other muscles innervated by the radial nerve, a more distal approach may be necessary.

The moments recorded from the fingers were lower than expected based on the observed hand opening. The subject tested had significant stiffness when extending the finger joints and these measurements were made with the fingers already partially extended. Both of these factors contributed to the low finger extension moment recorded. Visually, radial nerve stimulation was able to open the hand to the extent that the contractures allowed.

Conclusion

Percutaneous testing of the nerve cuff electrodes in this subject is complete. Additional moment measurements will be recorded to assess the longer term strength, stability and selectivity of the electrodes but current steering is not possible using the implanted stimulator. Detailed data analysis is still being performed on the data collected. This subject is currently working with members of the team to setup functional hand and arm stimulation patterns. The goal is to have the subject controlling her paralyzed arm using voluntary neck EMG signals. The percutaneous phase of this trial has been highly beneficial and demonstrated several key findings.

- Non-penetrating, multicontact cuff electrodes can selectively stimulate individual muscles within a common nerve trunk;
- Selectivity can be improved with current steering;

- Intraoperative testing of electrodes is a predictor of chronic performance;
- Muscle force production is stable or increases with exercise, indicating no adverse physiological consequences of the electrode implanted on the nerve;

Surgical Implantation of Dual Stimulator System in High Tetraplegia

Contract section: E.1.a.vi.4.3 Implementation of neuroprostheses for high tetraplegia

Summary

In this quarter, two 12-channel stimulators were successfully implanted in the upper extremity and trunk of a subject with high cervical level tetraplegia. The temporary percutaneous leads that were previously implanted were disconnected from the nerve cuff electrodes and the nerve cuffs were connected to the stimulator leads. Two additional nerve cuff electrodes were implanted, along with 15 additional intramuscular electrodes for stimulation of the muscles of the hand, forearm, and upper trunk. Four bipolar MES electrodes were also implanted on voluntary muscles for use as control signals.

Methods

The individual with a C1-level spinal cord injury on her right side, who had previously had four nerve cuff electrodes implanted with percutaneous leads (see QPR #18, Jul-Sept 2005), had two surgeries this quarter to complete the second phase of the implantation of the high tetraplegia FES system. In each of the two surgeries, the subject had a stimulator implanted which had 12 channels of stimulation and two bipolar myoelectric signal (MES) channels. This stimulator is referred to as the IST-12.

In the first of the surgeries, the IST-12 was placed in the abdomen caudal to the lowest rib. The previously implanted nerve cuff electrodes were disconnected from the percutaneous leads. Two of the nerve cuff electrodes (suprascapular and axillary) each had a single lead which was connected to one of the stimulator's channels. The other two nerve cuff electrodes had four separate leads (one for each contact). Based on the evaluation of the individual contacts via the percutaneous interface, the preferred contacts were connected to channels on the stimulator. For the musculocutaneous nerve, three of the contacts produced good elbow flexion. It was decided that one of the three was redundant, so two of the contacts were connected to the stimulator. The other two leads had silicon caps placed over their connector pins. For the radial nerve, three of the four contacts produced useful function, while the fourth did not. The three useful contacts were connected to the stimulator, while the fourth lead was capped.

Two additional nerve cuff electrodes were then implanted, each of which had a single lead. One was placed on the long thoracic nerve, to activate the serratus anterior muscle and provide scapular abduction. After exposing the long thoracic nerve and selecting an appropriate size cuff electrode (2 mm diameter), the spiral cuff was wrapped around the nerve and the electrode was stimulated. Since a good response was achieved from stimulation, the electrode lead was connected to the stimulator.

The other nerve cuff electrode was placed on the thoracodorsal nerve, to activate the latissimus dorsi muscle and provide arm adduction. After exposing the thoracodorsal nerve, another 2 mm diameter cuff electrode was selected and placed on the nerve (see Figure 8). A good response was also obtained with this electrode, so it was connected to the stimulator.

Three of the target muscles could be easily and adequately activated with intramuscular electrodes. One intramuscular electrode was placed in the rhomboids (for scapular adduction), and one each was placed in the upper and lower pectoralis (for shoulder horizontal flexion).

Each IST-12 has two MES channels that telemeter voluntary muscle signals to an external unit to be used as control signals. For an individual with a C1 level spinal cord injury, there are a limited number of muscle sites that are under voluntary control. It is also preferable that the voluntary muscle not be activated frequently during normal activities. For example, the muscles that turn the head would not be good MES signal candidates, since head movement would corrupt the MES control signal. The two MES recording sites for this IST-12 were the right platysma and the right auricularis. The platysma is on the neck and is used to make a facial grimace. The auricularis is behind the ear and is used to wiggle the ear. Not everyone is able to control the auricularis very well, but this particular subject had very good control of it. For each recording site, an incision was made over the intended muscle, and a bipolar epimysial electrode was sutured to the muscle.

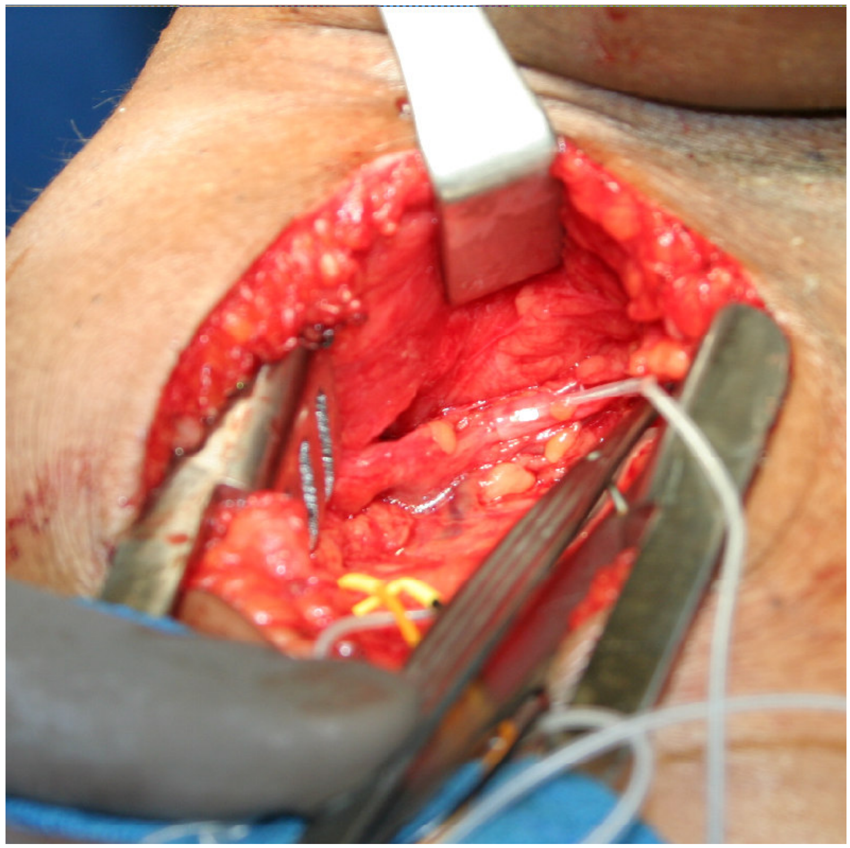

Figure 8. Spiral nerve cuff electrode placed on the thoracodorsal nerve to activate the latissimus dorsi.

Once all the electrodes were inserted or attached at the desired site, they were tested and then tunneled to the site of the stimulator in the abdomen. The leads were connected to the IST-12 and tested once more. One lead had been damaged during the procedure, but it was repaired using an implantable lead repair kit. After all the leads were connected and tested, the remaining incisions were closed. The wounds were dressed and the right arm was placed in a protective sling. A diagram of the stimulator with the stimulation channels and MES channels is shown in the lower portion of Figure 9. A list of the electrode placements and their functions is shown in the second half of Table 2.

Two days after the first stimulator implant surgery, a second surgery took place in which an IST-12 was placed in the chest. During this surgery there were also 12 intramuscular electrodes placed in the hand and forearm and 2 MES electrodes were placed in the left neck and upper trunk. As can be seen in the first half of Table 2 and the upper portion of Figure 9, the stimulation electrode sites are those that are typically selected for our upper extremity neuroprostheses. These include finger extensors and flexors; thumb extensor, flexor, and abductor; wrist flexor; and forearm supinator and pronator. For each muscle, an intramuscular probe is used to identify the desired placement, then the electrode is inserted into the muscle and is tested. The leads are then passed to connector sites in the upper arm and are connected to the stimulator.

As was the case with the earlier stimulator implant surgery, there are few candidate sites for the MES recording electrodes. It was decided to place the bipolar epimysial electrodes on the left platysma and the left trapezius muscles (Figure 9). These leads were also tunneled to the stimulator and connected. After testing each channel, the remaining incisions were closed. The wounds were dressed and the right arm was placed in a bi-valve cast and supported in a protective sling.

Results

Three weeks after surgery, the cast was removed and an initial profile of the electrodes was performed. All of the stimulation electrodes activated their target muscles at low stimulation values. Several of the electrodes could not have the stimulation turned up very high due to some remaining discomfort due to post-surgical swelling. Three of the four MES electrodes produced adequate signals. One MES electrode (the left trapezius) seems to produce a relatively small signal. Initial exercise patterns were programmed into a portable external control unit (ECU) that the subject could take home and perform daily exercise routines to strengthen the muscles. An additional mode was programmed into the ECU to allow the subject to practice controlling the MES signals. Rows of LEDs on the ECU provided feedback to the subject on the amplitude of the MES signals. The subject was then sent home to exercise and practice the MES control while continuing to recover from the surgeries.

Next Quarter

Once the subject has had further time to recover from the surgeries, further electrode profiles will be performed. Stimulation patterns will be set for hand grasps and for forearm, elbow, and shoulder motion. Control algorithms that use the four MES signals as inputs, predict the intended motion, and produce the corresponding stimulation patterns will be developed and tested.

Table 2. High Tetraplegia Dual-12-Channel-Stimulator Electrode Placement

	Muscle			Electrode
	Function	**Abbrev.**	**Full Name**	**Type**
Upper IST (Hand, Forearm)	Finger Flexor	FDPi	Flexor Digitorum Profundus - Index	Intramusc.
	Finger Flexor	FDS	Flexor Digitorum Superficialis	Intramusc.
	Finger Extension, Abduction	3DI	3rd Dorsal Interosseus	Intramusc.
	Finger Extension, Abduction	2DI	2nd Dorsal Interosseus	Intramusc.
	Finger Extension	EDC	Extensor Digitorum Communis	Intramusc.
	Thumb Flexor	AdP	Adductor Pollicis	Intramusc.
	Thumb Flexor	FPL	Flexor Pollicis Longus	Intramusc.
	Thumb Extension	EPL	Extensor Pollicis Longus	Intramusc.
	Thumb Abductor	APB	Abductor Pollicis Brevis	Intramusc.
	Wrist Flexor	PL	Palmaris Longus	Intramusc.
	Forearm Supination	Sup	Supinator	Intramusc.
	Forearm Pronation	PQ	Pronator Quadratus	Intramusc.
	MES Recording	LPlat	Left Platysma	Epimysial MES
	MES Recording	LTrap	Left Trapezius	Epimysial MES
Lower IST (Shoulder, Upper Arm)	Wrist Extension	Rad-WE	Radial Nerve, Wrist Extensors Fascicle	Cuff
	Wirst & Finger Extension	Rad-WE-FE	Radial Nerve, Wrist and Finger Extensors Fascicles	Cuff
	Elbow Extension	Rad-Tri	Radial Nerve, Triceps Fascicle	Cuff
	Elbow Flexion	M1	Musculocutaneous Nerve, Biceps & Brachialis	Cuff
	Elbow Flexion	M2	Musculocutaneous Nerve, Biceps & Brachialis	Cuff
	Arm Abduction	Ax-Delt	Axillary Nerve, Deltoid	Cuff
	Arm Adduction	Th-LD	Thoracodorsal Nerve, Latissimus Dorsi	Cuff
	Scapular Abduction	LT-SerAnt	Long Thoracic Neve, Serratus Anterior	Cuff
	Scapular Adduction	Rhomb	Rhomboids	Intramusc.
	Shoulder Stability, Humeral Rotation	SS	Suprascapular Nerve, Supraspinatus & Infraspinatus	Cuff
	Shoulder Horizontal Flexion	UpPec	Upper Pectoralis	Intramusc.
	Shoulder Horizontal Flexion	LoPec	Lower Pectoralis	Intramusc.
	MES Recording	RPlat	Right Platysma	Epimysial MES
	MES Recording	RAur	Right Auricularis	Epimysial MES

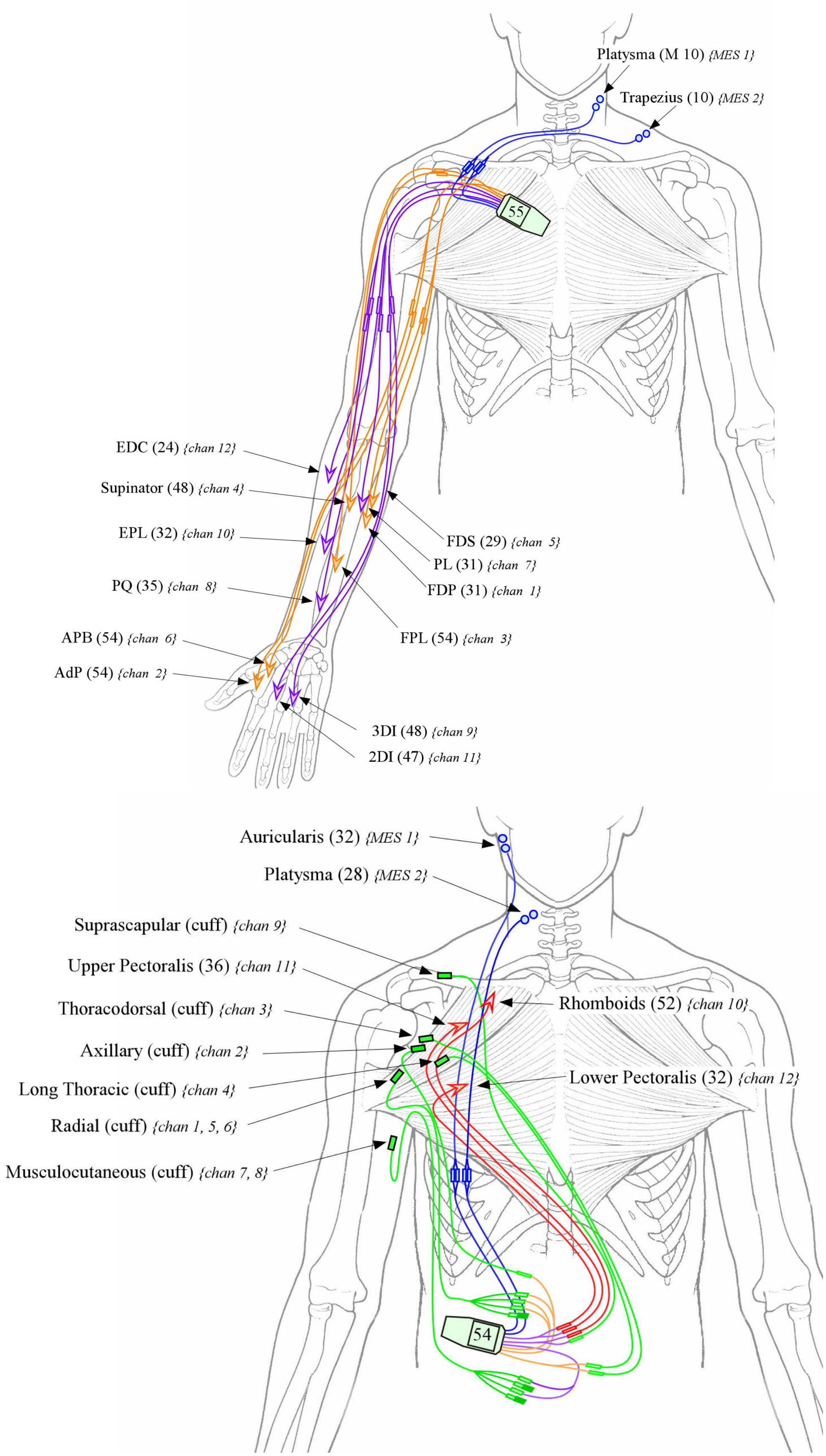

Figure 9. Diagrams of dual 12-channel stimulator systems.

Wireless Data Acquisition Module for Use with a Neuroprosthesis

Contract section: E.1.a.v Sensory feedback of contact and grasp force

Abstract

A general wireless data acquisition module (WDAM) is being developed for use with a neuroprosthesis. The WDAM is intended to be used with sensors such as the shoulder or wrist position transducer, finger-mounted joysticks, or remote on-off switches. Currently these sensors are connected to a controller via cables, which are cosmetically unappealing to the user and often get caught on wheelchairs, causing them to be damaged. Switch-activated transmitters mounted on walkers have been used previously in FES applications [1]. Recent advances in wireless technology have reduced the complexity and size of the wireless circuitry and have increased the likelihood that a small, low power, reliable wireless link could be assembled from commercially available components.

Methods & Results

In this quarter, the miniature WDAM that had been developed in the previous few quarters was characterized and compared to the earlier, larger WDAM versions. In addition, the miniature WDAM was used in a wireless joystick application with a custom enclosure.

<u>Current Draw</u>

Measurements were made of the current drawn by the miniature WDAM using a master-slave communication protocol, and when in sleep mode. The miniature WDAM draws a baseline of 1.2 mA, with pulses of 4.5 mA when receiving data and 12 mA when transmitting data. The RMS current draw was 2.3 mA. This compares favorably to the 2.6 to 3.4 mA RMS current measured in the earlier, larger WDAM versions. When the miniature WDAM is put into its sleep mode it draws 0.2 mA.

<u>Battery Longevity</u>

Battery longevity tests were performed using the same testing protocol as the previous WDAM versions (see QPR#11, Oct-Dec 2003, and QPR#14, Jul-Sept 2004). A master-slave software protocol was used. The miniature WDAM was the slave unit and was using a fully recharged lithium polymer battery (3.8 V). The master WDAM used an AC power adapter and was serially connected to a PC, which recorded the status at 5 minute intervals. The miniature WDAM transmitted continuous data (10 Hz) for over 60 hours. The stated capacity of the lithium polymer rechargeable battery is 180 mA-hr. An RMS current of 2.3 mA for 60 hours results in a 138 mA-hr capacity. However, since it is not a constant current draw, but a series of spikes of larger amplitudes, it is not surprising that the measured capacity is lower. It is anticipated that the device will not be used for more than 8 hours of continuous data transmission per day, so a longevity of 60 hours results in more than a week's worth of use before recharging.

Since the miniature WDAM does not have an on/off switch, it is put into sleep mode when not being used. Since the current draw during sleep mode was measured to be 0.2 mA, a 180 mA-hr battery should provide power for 37.5 days. To test the actual longevity in sleep mode, a fully-charged lithium polymer battery (3.8 V) was connected to a miniature WDAM, and the miniature WDAM was placed in sleep mode. Daily measurements of the battery voltage were made. The battery voltage slowly decreased for 26 days, until it reached its lower cutoff voltage value (the battery has internal protection circuitry). This test will be repeated, and if similar results are obtained, we will investigate why the battery longevity is less than expected. However, even with this measured longevity, the miniature WDAM can function after sitting on a shelf for over 3 weeks without charging.

Wireless Joystick Application

The miniature WDAM was incorporated into a wireless joystick application for a lower extremity FES project (see Figure 10). This entailed taking the force-sensing-resistor joystick and WDAM application that was demonstrated in an earlier QPR (QPR #13, Apr-Jun 2004), and designing a custom enclosure that allows the joystick and transceiver to be easily held in the hand. The enclosure was designed using the Solidworks 3D design software, and was fabricated using a Dimension 3D printer (Stratasys, Inc.). Initial testing indicated that the wireless joystick was operating as specified.

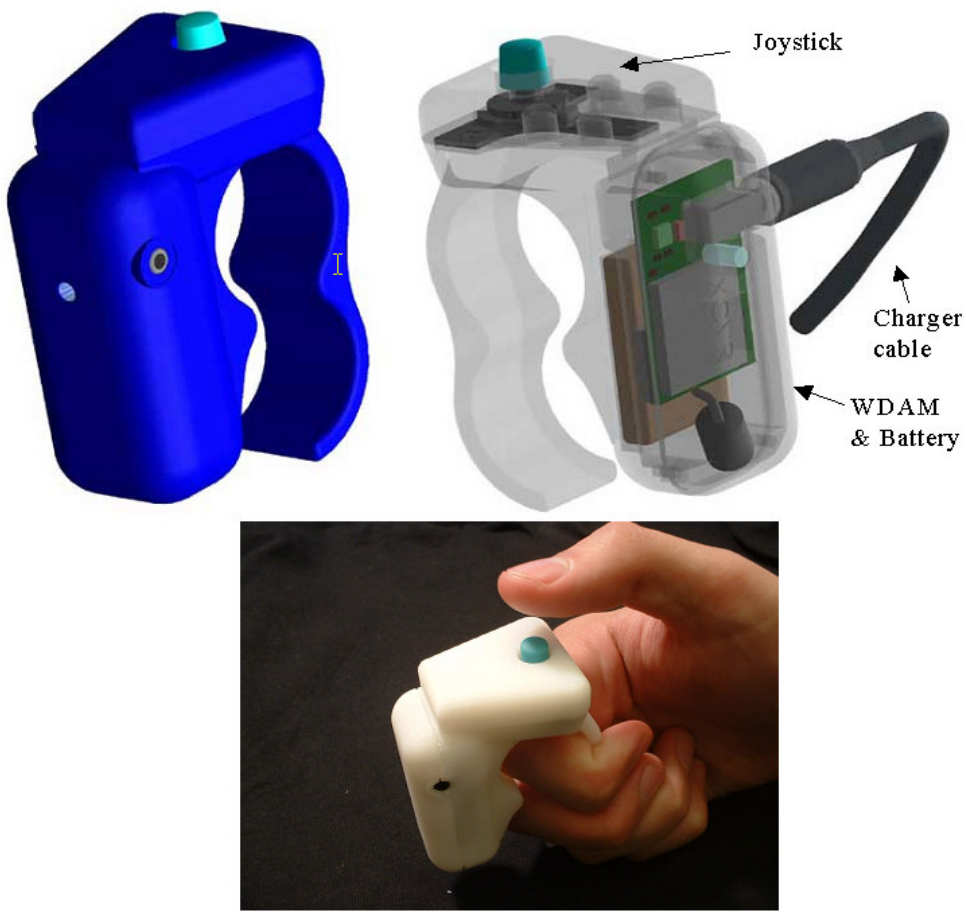

Figure 10. Wireless joystick enclosure

References

[1] Z. Matjacic, M. Munih, T. Bajd, A. Kralj, H. Benko, and P. Obreza, "Wireless control of functional electrical stimulation systems," *Artif Organs*, vol. 21, pp. 197-200, 1997.